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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,562

04/13/2007

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PS-5 US

1586

28581 7590 03/19/2010
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EXAMINER

GORDON, BRIAN R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,562	Applicant(s) HAUSHALTER ET AL.	
	Examiner Brian R. Gordon	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-17-09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on December 17, 2009 is acknowledged.

As indicated in the telephone message left for Paul Schwarz on March 10, 2010, Group I was previously indicated as including claims 1-21. However, Group I actually includes claims 1-17.

Claim Interpretations

2. As to claim 4, it should be noted that the claim does not specify the location of the surface. The "contacting" is directed to the intended use of the surface rather than defining the structure of the surface. Any surface of a tip can be referenced as a "contacting surface". One can choose to contact any surface of any tip with any other object one desires.

Claim Objections

3. Claims 6-8 and 15-17 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims do add any further structure to the device. claims 6 and 15, merely state the tip can be used to deposit fluid. There are no restrictions on the size of the dimensions of the pin. Claims 7-8 and 16-17 are directed to the volume of the liquid. The liquid is not a

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structural element of the pin of the tip. The claims are directed to the overall intended use of the printing tip.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 9, it is unclear how the external wall “leads” to the channel. It is unclear what the structural relationship of the wall and channel.

As to claim 11, there is no antecedent basis for “the step”. Are the step portion and the step the same element.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-5 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. US 2002/0094304 A1.

Yang et al. disclose an apparatus for dispensing a liquid includes a dispensing end, an adaptor end, and an elongate dispenser body extending therebetween. The dispenser body has a first major surface extending to the dispensing end. The dispenser body defines a fluid reservoir opening on the first major surface for receiving a fluid to be dispensed. The dispenser body also defines a first elongate open channel opening on the first major surface and extending between the fluid reservoir and the free end of the dispenser body. The first channel includes dimensions such that the fluid to be dispensed is conducted through the channel by capillary action (abstract, see figures).

FIG. 1 depicts a dispensing pen 10 of the present invention. Pen 10 includes a dispensing end 12, an opposed adaptor end 14, and an elongate pen body 16 extending therebetween. Pen 10 is particularly suited to dispense spots of sub-nanoliter volumes of DNA or biomolecules to create microarrays for use in high-through-put analysis.

Fluid channel 24 and fluid reservoir 22 desirably hold in the range of about 5 to about 100 nanoliters and may be formed to hold about 60 nanoliters of fluid sample. The volume of fluid retained by pen 10 is desirably sufficient to deposit about 100 spots of the fluid onto a substrate between loadings. Pen 10 has demonstrated forming spots of fluid in the range of about 50 to about 500 picoliter having a diameter in the range of about 50 to about 200 microns. For present purposes, the spots of fluid dispensed by pen 10 desirably include about 100 picoliters of sample fluid having a diameter of about

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120 microns. The dimensions and capacity of pen 10 are contemplated for all of the dispense pens of the present invention.

8. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Martinsky US 6,101,946.

Martinsky discloses a device for fabricating microarrays of biochemical substances, consisting of a holder and one or more printing pins. The holder contains apertures with regular spacing that define the location of one or more printing pins during the printing process. The tip of each printing pin contains a sample channel that holds a predetermined volume of biological or chemical sample and a point that is machined to precision with an electronic discharge machine (EDM). The device can be attached to a motion control system for precise and automated movement in three dimensions. The flat tips of the pins are immersed in a biochemical sample such that a predefined volume of sample fills the sample channel of each pin. The holder and pins are then moved in proximity to a printing substrate whereby direct contact between the flat tips of the pins and the surface results in the transfer of a small amount of the sample onto the solid surface. The holder and pins are mass produced at high precision to ensure that the printed elements in the resultant microarray contains approximately the same quantity of sample. In one preferred embodiment, the device is employed to manufacture arrays of nucleic acids or derivatives thereof (abstract).

The pin is comprised of two parts: the shaft 28 and the collar 24. The shaft 28 is made out of 440-C stainless steel. Series 400 stainless is preferable to softer grades of stainless steel, such as series 300 materials which tend to be less durable than series

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400 materials. Located on the lower, printing end of the shaft 28 is the point 20 of the pin. The point 20 of the pin is magnified in FIG. 3B to reveal a flat tip 32 and a sample channel 22. Referring again to FIG. 3A, the collar 24 is made out of 303 stainless steel and is located at the upper, non-printing end of the

The adjustment of the pin gap 30, shown in FIG. 3B, employs high precision tooling to hold the pin firmly and without damaging it (tapering of channel).

A reservoir 40 may also be incorporated within the device as seen in figure 4.

The invention employs custom sample channels that can be modified to hold sample volumes up to 1.0-2.0 microliters ($1.0-2.0 \times 10^{-6}$ liter). The capacity to use EDM to adjust the predefined volume of sample loaded allows the user to dictate the number of microarrays produced from a single loading. A typical pin, depicted in FIGS. 2A-2D, 3A, and 3B, will deposit approximately 1.0 nanoliter (1.0×10^{-9} liter) of biochemical sample, providing for approximately 200 microarrays for a sample channel 22 that holds 0.2 microliters (0.2×10^{-6} liter). Larger sample channels that contain an expanded sample reservoir 40, as shown in FIG. 4, would allow as many as 1,000 microarrays to be produced from a single loading.

Other embodiments of the present invention allow for larger printing points that deliver up to 10 nanoliters (10×10^{-9} liter) of biochemical substance. This is accomplished by altering the EDM cutting routine used to make the points. A point that has square outer dimensions of 3 mil.times.3 mil (0.003".X 0.003") will produce a circular microarray element that is approximately 4 mil (0.004") in diameter. A point that

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has square outer dimensions of 8 mil X 8 mil (0.008" X 0.008") will produce a circular microarray element that is approximately 10 mil (0.010") in diameter.

9. Claims 10 and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bousse et al., US 6,803,568.

Bousse et al. disclose a microfluidic body formed with a plurality of reservoirs for containing at least one fluid medium; a plurality of separated channels formed within the microfluidic body that are in fluid communication with a corresponding reservoir but are not in fluid communication with each other within at least a portion of the microfluidic body; and an electrospray ionization tip formed with an open-ended distal tip portion that is positioned along an end surface of the microfluidic body, wherein the plurality of separated channels converge at the open-ended distal tip portion to direct an ionization spray derived from the fluid mediums. (Claim 1). The device is composed of glass, quartz, ceramic, silicon, silica, silicon dioxide or other suitable material such as a polymer, copolymer, elastomer or a variety of commonly used plastics.

The tip portion of the device is clearly thinner than the other portion of the device that encompasses the reservoirs. The difference in the thickness of tip and other portion is created by a step portion. See figures.

10. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Brewer, US 6,566,145.

Brewer discloses a dispensing device that includes an upper reservoir portion connected to a tip via a tapered channel. See figures.

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11. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Overbeck et al., US 6,269,846.

Overbeck et al. discloses a pin depositing assembly that includes a reservoir connected to a tip via a taper channel (see figures 2 and 2A).

12. Claims 1-4 and 6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Gautsch, US 5,223,225.

Gautsch discloses a plastic, conical, dispensing device including a reservoir connected to a tip via a tapering channel. Furthermore the device includes multiple step portions and grooves 14. (See figures). The thickness profile shown in figure 2A shows the steps formed from portions of different thickness.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouse et al. as applied to claims 10 and 15-17 above, and further in view of Yang et al., Martinsky et al, Brewer, Overbeck et al. or Gautsch.

As to claim 1, Bouse et al. does not explicitly disclose tapered channels.

Yang et al., Martinsky et al, Brewer, Overbeck et al. or Gautsch disclose dispensing devices that include tapered channels.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize the channels may be tapered to control the flow of the liquid from the reservoir to the tip.

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al., Martinsky et al, Brewer, and Overbeck et al. as applied to claim 1 above, and further in view of Jager et al. US 3,164,304.

Yang et al., Martinsky et al, Brewer, and Overbeck et al. do not disclose external grooves.

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Jager et al. discloses a dispensing pin device that includes grooves 64 that allow for liquid to be retained on the tip of the pin.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that devices of Yang et al., Martinsky et al, Brewer, and Overbeck et al. to incorporate the grooves as taught by Jager et al in order to allow the liquid to remain attached thereto until removal is desired.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brian R Gordon/
Primary Examiner
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